Section 5

MAINTENANCE AND SERVICE TESTS

This section contains preventive maintenance information, a performance verification test (PVT), and battery maintenance information for the PCA Plus and Plus II Series Infuser.

5.1 PREVENTIVE MAINTENANCE

A preventive maintenance program promotes longevity and trouble-free operation of the infuser. Such a program should include periodic inspection of the infuser, exterior cleaning and sanitizing, and checking for proper operation of the infuser by performing the PVT in *Section 5.2.*

As a minimum requirement, clean the infuser after each use. Establish a regular cleaning schedule during use. In addition, clean the infuser and perform the PVT as part of any scheduled service or after any repair procedure.

5.1.1 INSPECTING THE INFUSER

Periodically inspect the infuser for signs of defects such as worn accessories, broken instrument connections, or damaged cables. Such an inspection is also applicable after repairing or during cleaning. Replace any damaged or defective external parts.

Inspect the following areas for missing or damaged parts and for cosmetic defects:

- ☐ Labels
- ☐ Cords
- ☐ Switches and touchswitches
- ☐ Velcro® straps
- ☐ External screws
- ☐ Case
- ☐ Pole clamp and pads
- ☐ Front panel
- ☐ Security door
- ☐ Accessories

5.1.2

CLEANING THE INFUSER

The following procedures are designed to maintain the infusion system, sustain infuser longevity, and promote trouble-free instrument operation.

Follow hospital protocol for establishing the infuser cleaning schedule.

WARNING

DISCONNECT THE INFUSER FROM AC POWER PRIOR TO CLEANING THE INSTRUMENT. FAILURE TO COMPLY WITH THIS WARNING COULD RESULT IN ELECTRICAL SHOCK.

CAUTION: Do not immerse the infuser in liquids. Immersion could damage the instrument. Do not allow liquids to enter the infuser electronics compartment.

CAUTION: Do not spray cleaning solutions toward any openings in the infuser.

CAUTION: Certain cleaning and sanitizing compounds may slowly degrade components made from some plastic materials. Using abrasive cleaners or cleaning solutions not recommended by Abbott Laboratories may result in product damage and, potentially, void the product warranty. Do not use compounds containing combinations of isopropyl alcohol and dimethyl benzyl ammonium chloride.

Clean the exposed surfaces of the infuser with a soft, lint-free cloth dampened with one of the cleaning solutions listed in *Table 5-1, Cleaning Solutions*, or a mild solution of soapy water. Remove soap residue with clear water. Do not use solvents that are harmful to plastic, such as isopropyl alcohol or acetone. Do not use abrasive cleaners.

CAUTION: To avoid infuser damage, cleaning solutions should be used only as directed in *Table 5-1*. The disinfecting properties of cleaning solutions vary; consult the manufacturer for specific information.

Table 5-1. Cleaning Solutions

Cleaning Solution	Manufacturer	Preparation
Vesphene® II se	Calgon Vestal Laboratories	Per manufacturer's recommendation
Manu-Klenz®	Calgon Vestal Laboratories	Per manufacturer's recommendation
Formula C™	Diversey Corporation	Per manufacturer's recommendation
Super Edisonite®	S. M. Edison Chemical Co.	Per manufacturer's recommendation
Household bleach	Various	Per hospital procedures; do not exceed one part bleach in ten parts water
LifeCare® Germicidal Towelette	Manufactured for Abbott Laboratories	Per manufacturer's recommendations; use undiluted

5.1.3
SANITIZING THE INFUSER

Sanitize the external surfaces of the infuser using a cleaning solution listed in *Table 5-1, Cleaning Solutions.*

CAUTION: Do not sterilize the infuser using heat, steam, ethylene oxide (ETO), or radiation; these methods may cause the instrument to malfunction.

Note: Not all cleaning solutions are sanitizers. Check product labeling.

5.2
PERFORMANCE VERIFICATION TEST

As a part of a preventive maintenance schedule, it is recommended that the performance verification test (PVT) be conducted periodically per hospital procedures for compliance to accreditation requirements.

The PVT is used for overall verification of infuser performance and as a diagnostic tool during infuser troubleshooting. The PVT can be used for diagnostic purposes during the troubleshooting of a malfunctioning infuser, and for verification of the overall performance of an infuser as part of a preventive maintenance schedule. In addition, the PVT should be used for performance verification before an infuser is returned to service after repair. If any malfunction is detected as a result of the PVT, refer to *Table 6-3, Troubleshooting with the PVT.*

Note: The PVT must be performed exactly as described in this manual to assure effective and reliable product evaluation information.

5.2.1
EQUIPMENT REQUIRED

The following equipment, or equivalent, is required to perform the PVT:

- ❑ Door key
- ❑ PCA vial, standard, List No. 6021-03
- ❑ PCA vial, empty, List No. 6021, modified to one ring
- ❑ PCA set, List No. 3559-01
- ❑ Graduate or marked test tube, readable to 0.2 mL increments or smaller
- ❑ Three-way stopcock, List No. 3233
- ❑ Digital pressure meter (DPM), (0 to 50 psig), Bio-Tek® DPM II
- ❑ Safety analyzer, Dynatech Nevada® 231D
- ❑ Butterfly, 21-gauge, List No. 4492
- ❑ Test cable, fitted with phone jack with individual banana plugs (compatible with patient control connector on rear of infuser) P/N 561-88416-001
- ❑ Parallel network, P/N 561-88419-001
- ❑ Digital multimeter (DMM) Fluke® Model 77

- ☐ Silicone oil, Dow Corning® No. 360, P/N 743-35070-001
- ☐ X-acto® knife

5.2.2
INSPECTION

Inspect the areas listed in *Section 5.1.1, Inspecting the Infuser*, for missing or damaged parts and for any cosmetic defects.

5.2.3
INFUSER TEST SETUP

WARNING

DURING TESTING, DO NOT CONNECT THE INFUSER TO A PATIENT.

To set up the infuser, proceed as follows:

1. Using the dual-lock mechanism, secure the infuser to an IV pole.

   Note: When the security door is locked, the infuser locks to the pole clamp and prevents its removal without a key.

2. Connect the system to AC power unless otherwise specified.
3. Connect the appropriate Abbott PCA set to an Abbott 30 mL PCA vial/injector.
4. Prime the vial and administration set. Hold the vial vertically with the administration set extending from the top. Slowly push down on the injector until all air is cleared from the vial and administration set.

   CAUTION: Make certain all caps on the vial and the administration set are removed and all clamps are open when priming syringe.

5.2.4
SERVICE TEST MODE TEST

Table 5-2, Service Tests, and *Table 5-3, Service Options*, provide a list of tests and options available in the service test mode. Each test displays prompting information on the LCD screen to serve as a guide through the test. Prompts and descriptions are shown in *Table 5-2*.

Note: The patient pendant must be connected to the infuser to complete the service test mode test.

To enter the service test mode, proceed as follows:

1. Confirm that the AC power symbol on the front panel is illuminated.
2. Turn the infuser off and enter the storage mode by opening the security door and pressing the [OFF/RECHG] touchswitch for approximately six seconds. The LCD screen should darken.

3. Press and hold the [YES/ENTER] touchswitch and the [ON] touchswitch simultaneously for approximately three seconds.

The LCD screen displays INT RAM TEST until **SERVICE TEST** appears. The LCD screen also displays the current software version and the total elapsed days since the infuser was placed in service.

Note: Tests are self-prompting, giving the option of repeating the test, or going to the next test.

Table 5-2. Service Tests

Test	Description
Software version	Infuser displays the software version to identify the revision level of the infuser program stored in EPROM
Elapsed days	Display reflects total days infuser has been in operation
Internal RAM	Microcomputer RAM is tested to assure data can be reliably written to and read from specific memory cells
External RAM ADRS	Test is performed to determine the integrity of the address lines used to select specific memory locations for data access
External RAM cell	Microcomputer RAM memory is tested
CPU	Test routine is performed and the test results are verified to assure that the microcomputer is executing instructions properly
ROM	Checksum is calculated and compared to a pre-stored and pre-calculated value to assure the operating program residing in EPROM is intact
Real-time clock	Real-time clock is tested to verify its accuracy
LED	Pattern of 1s through 9s is displayed by the LEDs to verify operation
LCD	Non-displaying test pattern is written to the LCD RAM and compared with a stored pattern to assure that the LCD screen can accurately display data
Keypad	Stuck key test determines if any of the keys are permanently shorted. Press individual keys to determine if the key operates and the microcomputer recognizes the correct key. Test patient pendant pushbutton
Indicator	Test verifies battery and AC symbols are turned on and off when the power cord is connected and disconnected
Alarm	Audible alarm signal is generated to verify the alarm circuitry
Motor rotation	Motor is rotated a given amount and the shaft sensor signal is checked by the motor control circuitry

Table 5-2. Service Tests	
Test	**Description**
Security door	Test verifies the microcomputer recognizes when the security door is locked or unlocked
Syringe test	Test verifies the microcomputer can detect the presence and proper positioning of the vial and injector in the syringe driver mechanism
Empty syringe	Test verifies the microcomputer detects an empty syringe
Low syringe	Test verifies the microcomputer detects a low syringe (PCA Plus only)

Table 5-3. Service Options	
Option	**Description**
Patient pendant tone selection	Selection provides one of the following options: 1. Tone with successful PCA dose only (default) 2. Tone on all attempted PCA doses (placebo)
12 hour clock selection (PCA Plus only); 12/24 hour clock selection (PCA Plus II Series)	Selection provides one of the following options: 1. Clock format: 12 hour 2. Clock format: 24 hour
Select RX concentration (3.1 software and higher)	Selection provides one of the following options: 1. Milligrams only 2. Milligrams and micrograms 3. Drugs, milligrams, and micrograms

5.2.5

DELIVERY ACCURACY TEST

To perform the delivery accuracy test, proceed as follows:

1. Using a PCA vial/syringe with a primed PCA administration set and a 21-gauge butterfly; insert the vial into the infuser vial holder and injector cradle.
2. Purge the infuser at start up, then set up the infuser for 1 mg/mL. Place the butterfly in the graduate. Initiate two loading doses of 10 mL each.
3. Verify the infuser delivers 20 ± 1 mL in the graduate.

5.2.6

OCCLUSION TEST

To perform the occlusion test, proceed as follows:

1. Remove the plunger from the syringe. Using an X-acto knife, cut the two top ribs off the syringe plunger, as shown in *Figure 5-1, Modification of Syringe Plunger.* Make certain that no rough material is loose on the plunger.
2. Apply a light coating of silicone oil to the remaining rib. Replace the plunger in the syringe.
3. Insert the water-filled modified vial with the primed PCA administration set into the cradle assembly. Lubricate the vial with silicone oil before each use.
4. Attach the DPM to the distal end of the administration set through the three-way stopcock.
5. Allow the infuser self test to complete. When the LCD screen displays PURGE THE SYSTEM NOW?, press the [SILENCE/NO] touchswitch.
6. When the LCD screen displays DRUG: Rx MORPHINE 1 MG/ML ? YES OR NO, press the [YES/ENTER] touchswitch.
7. When the LCD screen displays ADMINISTER LOADING DOSE NOW?, press the [YES/ENTER] touchswitch.
8. Select loading dose of 5 mg. Press the [YES/ENTER] touchswitch, then press the [LOADING DOSE] touchswitch.
9. Observe fluid discharge at the end of the stopcock, then close the stopcock.
10. Verify the infuser sounds an alarm and flashes the OCCLUSION message when the pressure gauge indicates the following:

    -008 and lower: 14.0 to 19.0 psig (96.6 to 131.1 kPa)
    -010 and higher: 12.5 to 17.5 psig (86.25 to 120.75 kPa)
11. Open the stopcock to clear the OCCLUSION alarm.
12. Press the [HISTORY] touchswitch and check for correct time; if incorrect, refer to the system operating manual for information on resetting the time.
13. Clear all dose history data from memory by holding down the [OFF/RECHG] touchswitch until the LCD screen, including the backlighted grid, goes blank.

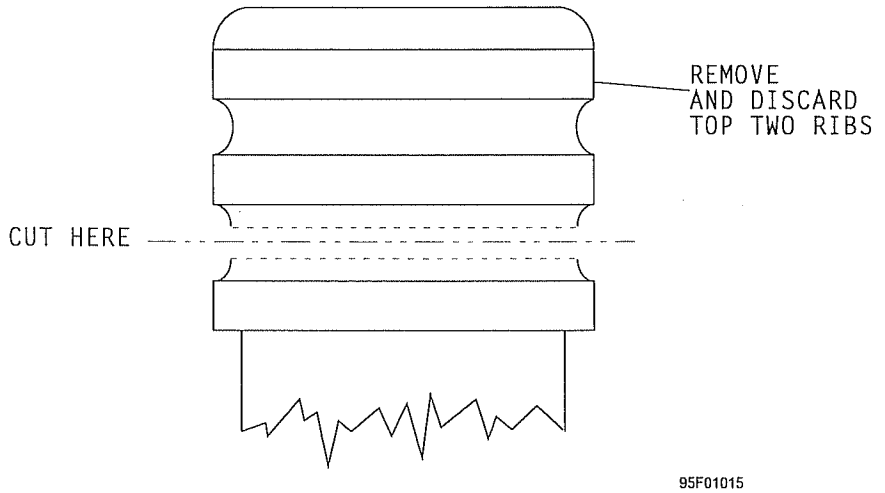


Figure 5-1. Modification of Syringe Plunger

5.2.7

PCA + CONTINUOUS TEST

To perform the PCA + CONTINUOUS test, proceed as follows:

1. Remove the modified vial from the cradle assembly and set up a standard water-filled vial with a 21-gauge butterfly on the distal end of the set.

   CAUTION: Do not remove the protective cover from the butterfly needle.

2. Insert the vial into the cradle assembly.
3. When the LCD screen displays PURGE THE SYSTEM NOW?, press the [SILENCE/NO] touchswitch.
4. When the LCD screen displays DRUG: Rx MORPHINE 1 MG/ML ? YES OR NO, press the [YES/ENTER] touchswitch.
5. When the LCD screen displays ADMINISTER LOADING DOSE NOW?, press the [YES/ENTER] touchswitch.
6. Select loading dose of 1 mg. Press the [YES/ENTER] touchswitch, then press the [LOADING DOSE] touchswitch.
7. When the LCD screen displays SELECT MODE PCA ONLY?, press the [SILENCE/NO] touchswitch.
8. When the LCD screen displays SELECT MODE CONTINUOUS?, press the [SILENCE/NO] touchswitch.
9. When the LCD screen displays SELECT MODE PCA + CONTINUOUS?, press the [YES/ENTER] touchswitch. Set PCA dose of 1 mg. Press [YES/ENTER].
10. Select a lockout interval of five minutes, then press [YES/ENTER].
11. Select a continuous rate of 20 mg/hr, then press [YES/ENTER].
12. When the LCD screen displays 4 HOUR DOSE LIMIT SET?, press [YES/ENTER].
13. Select a 4 HOUR DOSE LIMIT of 1.5 mg, then press [YES/ENTER].
14. Press the [HISTORY] touchswitch to confirm that the infuser settings are as specified. Close and lock the security door; the display should read: DOOR LOCKED - TOTAL DELIVERED 1 mg.
15. Press the [RESET/START] touchswitch. Verify that the walking bar appears in the LED window, indicating CONTINUOUS mode delivery. Verify that three asterisks appear in the upper left corner. The asterisks indicate PCA dosing is available.
16. Press the patient pendant pushbutton to deliver a PCA dose; verify that a beep sounds and PCA + CONTINUOUS displays. Verify the walking bar appears in the LED window.
17. After approximately two minutes, verify the four hour dose limit has been reached and the KVO rate has begun. Verify the TOTAL DELIVERED displays 2.5 mg.

    Note: If delivered prior to setup, the loading dose is not included in the four hour dose limit.

18. Press the patient pendant pushbutton three times; the infuser should not respond.
19. Unlock the security door and remove the injector from the holder; verify that the CHECK INJECTOR message flashes. Reseat injector and verify that the CHECK INJECTOR message disappears.

20. With the security door unlocked, pull the top of the vial away from the vial holder; verify that the CHECK VIAL message flashes. Reinsert the vial and verify that the CHECK VIAL message disappears.
21. Remove the vial from the cradle. Clear all dose history data from memory by holding down the [OFF/RECHG] touchswitch until the LCD screen, including the backlighted grid, goes blank.

5.2.8

PATIENT CONTROL JACK TEST

To perform the patient control jack test, proceed as follows:

1. Disconnect the patient pendant cable from the patient control jack on the back of the infuser.
2. Connect the test cable phone jack to the patient control connector; connect the leads on the other end of the cable to the terminals of the DMM as appropriate. Set the DMM to 10 volt DC scale.
3. Turn on the infuser and verify a DMM reading of greater than or equal to 4.5 VDC. Remove the test cable from the infuser.

5.2.9

PATIENT PENDANT ASSEMBLY TEST

To perform the patient pendant assembly test, proceed as follows:

1. Disconnect the patient pendant from the patient control jack on the back of the infuser.
2. Unscrew the shield from the patient pendant phono plug.
3. Set the DMM to measure continuity, then attach a DMM test lead to each patient pendant phone plug connection (polarity is not critical).
4. Press and hold the patient pendant switch. Verify the DMM displays continuity (0 ohm) and the continuity beeper sounds.

   Note: A value of up to 3 ohms may be indicated due to patient pendant cable assembly internal resistance.

5. Press and hold the patient pendant switch. Grasp the patient pendant cable approximately 4 inches (10 cm) above the patient pendant switch and rotate the cable three to four times while bending it approximately 30 degrees. Verify the DMM continues to display continuity.
6. Press and hold the patient pendant switch. Grasp the patient pendant cable approximately 4 inches (10 cm) above the phone plug and rotate the cable three to four times while bending it approximately 30 degrees. Verify the DMM continues to display continuity.
7. Release the patient pendant switch. Verify the DMM displays infinity (maximum resistance).
8. Connect the patient pendant cable to the patient control jack. Secure the locking nut (if applicable).

5.2.10
BATTERY CHARGER TEST

To perform the battery charger test, proceed as follows:

1. Disconnect the infuser from AC power.
2. Remove the battery cover and disconnect the battery.
3. Connect the parallel network to the charging circuit connector.
4. Connect the infuser to AC power. Power on the infuser. Measure voltage across the network; the DMM should read 9.4 ± 0.15 VDC (14.5 ± 2 VDC with a battery boost charger PWA).

   Note: The infuser must be powered on before obtaining the DMM reading.

   Note: See *Section 4.2.3, Battery Boost Charger PWA*, to identify infuser configurations with a battery boost charger PWA.

5. Remove the parallel network. Reconnect and re-install the battery; make certain the battery wires are not pinched. Re-install the battery cover.

5.2.11
ELECTRICAL SAFETY TEST

To perform the electrical safety test, proceed as follows:

1. Connect the AC power cord to an approved safety analyzer. Leakage current must not exceed 50 microamperes, but must be greater than 2 microamperes (open ground).
2. Using the safety analyzer, measure the resistance between the ground lug of the AC connector and exposed metal parts, such as the door key lock, patient pendant connector, or the exposed screw heads on the pole clamp. Note that the door hinge is not grounded. Resistance should not exceed 0.1 ohm.

Note: Exposed metal on the infuser is isolated from ground.

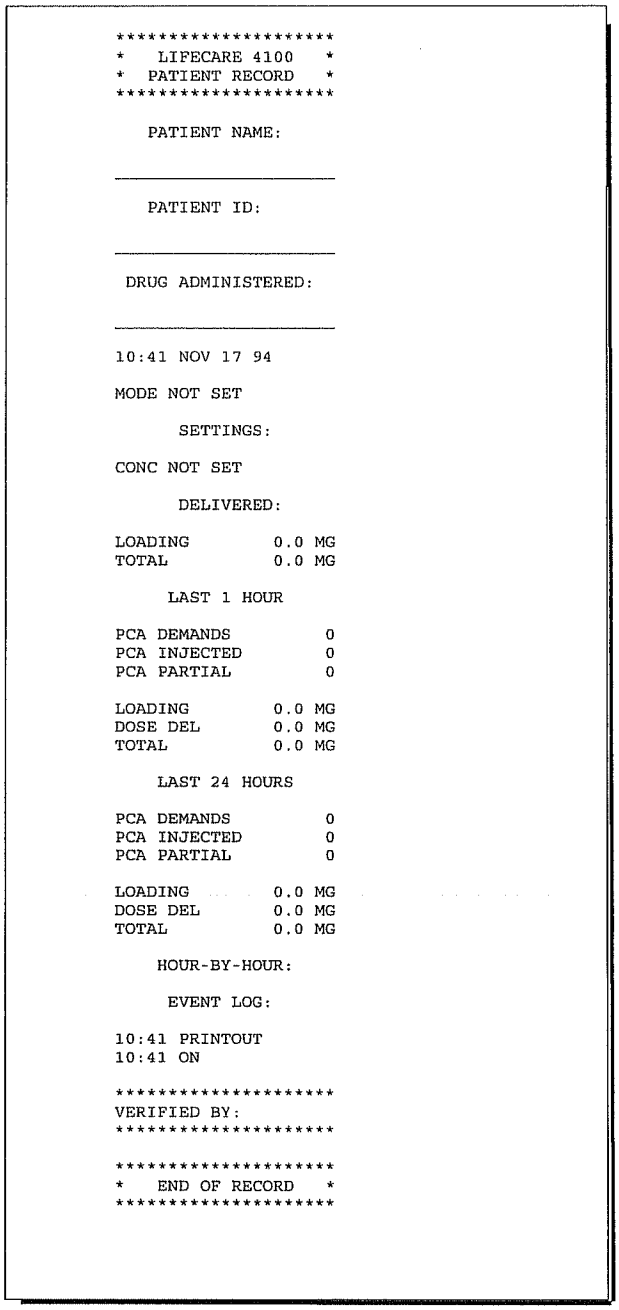
5.2.12

PRINTER TEST

To perform the printer test, proceed as follows:

1. Connect the infuser to AC power.
2. Connect the printer cable (Centronics interface) to the printer port located on the back of the infuser.
3. Power on the printer and verify it is on line.
4. Open the infuser security door, then insert the syringe into the cradle assembly. Verify the infuser begins the self test.
5. After the self test completes, the PURGE SYSTEM NOW? prompt displays. Press the [PRINT] touchswitch.
6. Confirm END OF RECORD is printed on the history and event log printout. It may be necessary to take the printer off line, then form feed the last partial page of the printout from the printer.
7. Compare the printout to *Figure 5-2, Sample Printer Test.* Date, time, and parameters will vary.

Note: Depending on the infuser configuration or the software revision level, the printout may not have an HOUR-BY-HOUR: entry.



```
**********************
*   LIFECARE 4100    *
*  PATIENT RECORD    *
**********************

   PATIENT NAME:

_____________________

   PATIENT ID:

_____________________

 DRUG ADMINISTERED:

_____________________

10:41 NOV 17 94

MODE NOT SET

      SETTINGS:

CONC NOT SET

      DELIVERED:

LOADING          0.0 MG
TOTAL            0.0 MG

     LAST 1 HOUR

PCA DEMANDS            0
PCA INJECTED           0
PCA PARTIAL            0

LOADING          0.0 MG
DOSE DEL         0.0 MG
TOTAL            0.0 MG

    LAST 24 HOURS

PCA DEMANDS            0
PCA INJECTED           0
PCA PARTIAL            0

LOADING          0.0 MG
DOSE DEL         0.0 MG
TOTAL            0.0 MG

    HOUR-BY-HOUR:

     EVENT LOG:

10:41 PRINTOUT
10:41 ON

**********************
VERIFIED BY:
**********************

**********************
*   END OF RECORD    *
**********************
```

Figure 5-2. Sample Printer Test

5.2.13

END OF PERFORMANCE VERIFICATION TEST

At the end of the PVT, clear all dose history data from memory by holding down the [OFF/RECHG] touchswitch until the display goes blank. If all tests have been successful, return the infuser to service. If any of the tests fail, refer to the troubleshooting information in *Section 6, Troubleshooting*, or contact Abbott Laboratories.

5.3
PVT DATA FORM

List Number: _____Serial Number: _____

Inspection

1.	Verify that all labels are on the infuser.	Pass___ Fail___
2.	Inspect the electrical cord for damage or foreign material.	Pass___ Fail___
3.	Verify that the control panel switches have no cracks or other damage.	Pass___ Fail___
4.	Verify that the two Velcro straps are present and not damaged.	Pass___ Fail___
5.	Verify that all screws are secured and tight.	Pass___ Fail___
6.	Inspect the case for cracks or stains.	Pass___ Fail___
7.	Inspect the pole clamp and pads for damage.	Pass___ Fail___
8.	Verify that the front panel has no cracks or cosmetic defects.	Pass___ Fail___
9.	Verify that the two bottom pressure pads are present and do not show excessive wear.	Pass___ Fail___
10.	Inspect the security door for any cracks or other damage.	Pass___ Fail___
11.	Inspect the patient pendant for cracked connector housing or cable damage.	Pass___ Fail___

Service Test Mode

1.	Record software version _____	
2.	All tests in service mode pass successfully.	Pass___ Fail___

Delivery Accuracy Test

1.	Set up PCA for a concentration of 1 mg/mL. Deliver two loading doses of 10.0 mL (Total = 20.0 mL) and verify delivery accuracy. Record _____ mL (specification = 19.0 to 21.0 mL)	Pass___ Fail___

Occlusion Test

1.	Initiate 5 mg loading dose and verify occlusion alarm and flashing OCCLUSION message. Record _____ psig Specification: -008 and below: 14.0 to 19.0 psig (96.6 to 131.1 kPa) -010 and above: 12.4 to 17.5 psig (86.25 to 120.75 kPa)	Pass___ Fail___

PCA + Continuous Test

1.	Verify the walking bar is displayed during continuous mode delivery.	Pass___ Fail___
2.	Verify that three asterisks appear in the upper left corner, indicating PCA dosing available.	Pass___ Fail___
3.	Verify a beep occurs and PCA + CONTINUOUS is displayed when the pendant is pressed.	Pass___ Fail___
4.	Approximately two minutes after pressing the patient pendant, verify that 4 HR LIM REACHED is displayed, KVO rate begins, and TOTAL DELIVERED display reads 2.5 mg.	Pass___ Fail___
5.	Verify that after pressing patient pendant three more times, there is no response from the infuser.	Pass___ Fail___
6.	Verify that by pulling the syringe vial away from the holder, a check vial alarm occurs.	Pass___ Fail___
7.	Verify that by pulling the syringe injector away from the injector holder, the check injector alarm occurs.	Pass___ Fail___

Patient Control Jack Test

1. Verify that the patient control input measures greater than or equal to 4.50 VDC. Pass___ Fail___

Patient Pendant Assembly Test

1. Connect DMM to patient pendant phone plug connections. Set DMM to measure continuity. Press and hold the patient pendant switch and verify the DMM displays continuity. Pass___ Fail___
2. Press and hold the patient pendant switch while rotating the control cable. Verify the DMM displays continuity. Pass___ Fail___
3. Press and hold the patient pendant switch while rotating the control cable. Verify the DMM displays continuity. Pass___ Fail___
4. Release patient pendant switch. Verify DMM displays infinity. Pass___ Fail___

Battery Charger Test

1. Connect the parallel network and measure the charger voltage across the network. Record _____ VDC Pass___ Fail___
   Specification:
   9.4 ± 0.15 VDC without battery boost circuit
   14.5 ± 2.0 VDC with battery boost circuit

Electrical Safety Test

1. Record leakage current. _____ Pass___ Fail___
   Acceptable result 50 µA.
2. Record ground lug resistance. _____ Pass___ Fail___
   Acceptable result 0.1 ohms.

Printer Test

1. Confirm END OF RECORD is printed on the history and event log printout. Pass___ Fail___
2. Compare the printout to *Figure 5-2, Sample Printer Test.* Pass___ Fail___

Performance Verification Test performed by _____Date:_____

Test Equipment:

Pressure Meter # _____

Safety Analyzer # _____

DMM # _____